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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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### CLEARINGHOUSE RULE 17-046

#### Comments

**[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]**

#### **1. Statutory Authority**

Section 299.11 (9), Stats., requires the department to promulgate *by rule* a graduated schedule of fees. However, in s. NR 149.21 (2) (b), the proposed rule appears to allow the department to establish a schedule of fees and revise the schedule annually without promulgating these fees in rule. That provision seems to apply to both the dollar amounts and certain aspects of the formula of a fee schedule. The department should: (a) describe and more clearly delineate its distinction between the dollar amounts and the formula that are the two components used in setting the fee schedule; (b) explain any authority for the dollar amounts to be set by internal policy rather than by rule; and (c) specify that revisions to the formula are limited to only revisions that are made by rule.

#### **2. Form, Style and Placement in Administrative Code**

a. In the introductory clause for the proposed rule that enumerates the provisions treated by the proposal, the designation “ch.” should be inserted before the citation to “NR 149”.

b. The purpose of the provisions under s. NR 149.04 is unclear. It appears that the text under sub. (1) is not a disclaimer, but a substantive restriction applicable to accredited laboratories. The title of this section should be revised and subs. (2) through (4) should be eliminated or relocated.

c. In s. NR 149.09 (3), the requirements for the department to engage the council for advice on various matters should be separated from the list of materials to be provided annually to the council.

d. In s. NR 149.13 (title), the parentheses should be removed from the phrase “certification and registration”. If necessary to set the parenthetical material apart, use a comma, semicolon, or long dash. This comment applies to other section and subsection titles as well, which should be reviewed.

e. In s. NR 149.13 (1), the source designation “, Stats.” should be inserted after the reference to s. 299.11 (8).

f. In s. NR 149.14 (4), consider combining pars. (b), (c), and (d) into one paragraph and three subdivisions, with an introductory phrase that the labs shall “do all of the following.”.

g. In s. NR 149.19, consider moving the requirement under sub. (9) to be separate from the section heading “Requirements for certification in the drinking water matrix” as this is not a certification requirement.

h. Similarly, consider revising s. NR 149.20 (title) since the provisions that follow do not appear to be “requirements for accreditation”.

i. Is the language in s. NR 149.21 (1) intended as an introduction to how the fee schedule is structured? The listed items should be explained in relation to how each item is addressed in other parts of the proposed rule. The phrasing that “The Department shall establish a schedule of fees” is confusing as it does not specify whether that phrase refers to the fee items contained in the proposed rule or to some other action that the department must take. Also, a title should be inserted for the subsection in order to be consistent with the use of titles for the other subsections in that section. Alternatively, consider removing sub. (1) entirely.

j. In ss. NR 149.444 and 149.446, the repeating phrase in the first part of each subsection title could be removed. The subject matter is already identified in the respective section titles.

k. A number of places in the proposed rule refer to and incorporate certain provisions of the Code of Federal Regulations. Standards from secondary materials may, in certain circumstances, be incorporated or updated with the consent of the Attorney General. At the end of the rule summary, the department should complete the unfinished comment on its compliance with that requirement. [s. 2.08 (5), Manual.]

## **5. Clarity, Grammar, Punctuation and Use of Plain Language**

a. All references to the department “reserving the right” or “retaining authority” to take an action should be eliminated from the rule proposal. These provisions should instead state the actions that the department is authorized to take, and the circumstances under which it may take them.

b. All instances of the phrases “however named”, “however conceived”, or other similar phrases, should be eliminated from the rule proposal.

c. In s. NR 149.02 (7) (c) and (d), who is to initially decide whether or not it is “apparent” which requirement is more restrictive? Does this require communication between the laboratory

and the department? This should be specified. Also, in these paragraphs and par. (b), the department should cite the sources of the methods, regulations, or covered programs referenced.

d. Consider revising s. NR 149.02 (7) (e). What is meant by “order of applicability” and “succeeding source”? And what effect does conflict between various sources have on the requirements applicable to a lab under this provision?

e. In s. NR 149.02 (7) (f), what process will the department use to determine acceptability of an alternate procedure? The grounds for accepting an alternate procedure should be specified.

f. In the proposed definition of “Acceptance limits”, where can the limits “established by the department” be found? The source of these limits should be cited.

g. In the proposed definition of “Laboratory”, what process will the department use to determine whether satellite labs within the specified distance of a principal lab will be considered part of a principal laboratory for purposes of accreditation?

h. In the proposed definition of “Matrix spike”, the second sentence should be revised to be descriptive.

i. A definition for the acronym “PT” should be incorporated into the proposed definition of “proficiency testing sample”, or created as a separate definition. The term “PT” is used in the proposed rule, and appears to be distinct from “PT sample”. Alternatively, consider revising the use of the term “PT” in the proposed rule to instead use the term “PT sample”, for consistency, if appropriate.

j. The proposed definition of “Qualify” should be written more plainly. For example, consider removing both commas, replacing the word “identifying” with the phrase “to identify”, and inserting the phrase “that were” before the word “encountered”. Also, should the phrase “the standards given in” be inserted after the word “from”?

k. The proposed definition of “Signature” should be removed as that term is not used in the proposed rule.

l. In the proposed definition of “Suspension”, the phrase “that may not require an on-site evaluation for reinstatement” is a substantive provision that should be removed from the definition.

m. The proposed rule should be reviewed and revised for consistent use of defined terms and acronyms throughout the substantive provisions.

n. In s. NR 149.05 (4), the department should specify the process that it will use to determine whether to approve accreditation transfer.

o. In s. NR 149.06 (2) (b), what is meant by a “contractor of a laboratory”?

p. In s. NR 149.06 (2) (c), the word “accredited” should be inserted before the phrase “under this chapter”.

q. In s. NR 149.06 (3), the department should specify the effect of “recognition” of labs.

r. In s. NR 149.10 (1), (2), and (3), the department should explain what is meant by “materially and consistently”.

s. Are the circumstances listed in s. NR 149.11 (2) and (3) intended to be the only exceptions allowed under sub. (1)? The relationship between subs. (2) and (3) and sub. (1) should be specified.

t. In s. NR 149.12 (4), the department should specify the grounds it may use to repeal a variance and the circumstances in which it may make that reconsideration.

u. In s. NR 149.13 (4) (b) and elsewhere in the rule proposal where a covered program participates in the regulatory process of laboratories in some way, specify how, or by whom, a request or action would be made on behalf of a “covered program”.

v. Consider rephrasing s. NR 149.14 (1) (a) (intro.) to be in the active voice.

w. In s. NR 149.14 (1) (a) 7. and (e), the department should specify what additional information might be required of an applicant, and under what circumstances.

x. In s. NR 149.14 (1) (b) 3., replace “nonconformance’s” with “nonconformances”.

y. In s. NR 149.14 (1) (d), consider rephrasing the language from considering an application to be “void” to considering an application to have “expired”.

z. In s. NR 149.14 (3) (title), consider replacing the word “applications” with the word “accreditations”.

aa. In s. NR 149.14 (3) (c), remove the phrase “to effect the conversion”.

bb. Consider revising s. NR 149.18 (1) to be phrased more plainly.

cc. In s. NR 149.19 (5) (b), what is meant by “which it repeatedly fails”? This standard should be specified.

dd. In s. NR 149.22 (1) (a) (intro.), it appears that the word “any” should be replaced with “all”. The rule should be reviewed and similar changes should be made where the word “any” is used in an introductory clause when the regulated laboratory must meet all of the listed requirements that are applicable to that lab. This may necessitate revision of the listed requirements under these introductory clauses.

ee. In s. NR 149.28 (2), it appears that the word “be” should be removed.

ff. In s. NR 149.29 (2) (a), what is meant by requiring an application to be “satisfactory”?

gg. In s. NR 149.30 (2), what is meant by “voluntarily appraise the evaluation process”?

hh. In s. NR 149.31 (1), the phrase “identified during” should replace the word “of”.

ii. In s. NR 149.365 (intro.), the word “under” should replace the phrase “as presented in”.

jj. Section NR 149.38 (6) should be revised to clearly indicate what actions are required by laboratories taking corrective action. Any other text should be removed or put into a note following the provision.

kk. In s. NR 149.42 (3) (e) 1., a possessive apostrophe should be inserted at the end of the word “weights”.

II. In s. NR 149.42 (4), is the “laboratory accreditation program” intended to mean something different from “the department”?